

REMARKS

This Amendment cancels claims 1-17 and adds new claims 18-30. The new claims correspond to claims 1-13. Claims 18-30 are pending.

This Amendment cancels non-elected claims 14-17. Reconsideration and withdrawal of the restriction requirement are respectfully requested.

The 35 U.S.C. 102(e) rejection of claims 1-5 and 9 over U.S. Patent No. 6,568,286 to Cabuz is traversed. The claimed assay includes retaining biological particles containing an analyte(s) of interest on a filter, followed by removing the biological particles from the filter by a flush flow in a second direction opposite said first direction, and then analyzing biological particles contained in the flush flow by means of a nucleic acid amplification assay.

Cabuz fails to disclose these steps of the claimed assay. Col. 2, lines 39-58, cited by the Patent Office, do not disclose or suggest retaining biological particles *containing the analyte(s) of interest by a filter*. Instead, Cabuz appears to disclose the use of bi-directional flow to clean filters of particulate contaminants (Col. 9, lines 29-31). Its bi-directional "shallow breathing" mode does not appear to include filtering the sample at all, and

certainly does not retain biological particles containing analyte(s) of interest on a filter. See col. 9, lines 61-67.

Reconsideration and withdrawal of the anticipation rejection of claims 1-5 and 9 over Cabuz are respectfully requested.

The 35 U.S.C. 103(a) rejection of claims 6-8 and 10-13 over Cabuz in view of Iqbal et al., 15 Biosensors and Bioelectronics 549 (2000) is traversed. The claimed nucleic acid amplification assay includes the step of retaining biological particles containing an analyte(s) of interest on a filter, followed by removing the particles from the filter by a flush flow in a second direction opposite said first direction, and then analyzing the biological particles contained in the flush flow by means of a nucleic acid amplification assay.

The claimed assay provides a novel and simple way to detect specific analytes (nucleotides such as DNA and RNA) within intact biologic particles such as bacterial cells. The biological particles are used as vessels for the analytes. There is no need to extract or expose the target nucleic acid prior to the nucleic acid analysis step, and thus no need for the nucleic acid separation or isolation steps which are currently viewed as state-of-the-art methods.

The claimed assay thus solves the challenge posed by Iqbal et al.:

Various nucleic acid-based methods have been developed for detection of enteric pathogens. Few have potential to serve outside the laboratory, i.e., in the field. Although state of the art nucleic acid based methods are very specific and sensitive, they are not currently adaptable to field applications. The challenge is to develop a method which selectively purifies the target nucleic acid and removes inhibitors from the sample.

Iqbal et al. at page 565, section 3.2.1., first paragraph (emphasis added).

Neither Cabuz nor Iqbal et al. provide an answer to Iqbal et al.'s challenge. Moreover, the combination of these references fails to raise a prima facie case of obviousness against the claimed assay. As discussed above, Cabuz fails to disclose (or suggest) retaining biological particles containing the analyte(s) of interest on a filter, followed by removing the particles from the filter by a flush flow in a second direction opposite said first direction, and analyzing biological particles contained in the flush flow by means of a nucleic acid amplification assay.

The deficiencies of Cabuz are not remedied by Iqbal et al., which also fails to disclose or suggest filtering a sample to collect biological particles containing the analyte of interest, removing the particle from the filter by a flush flow in the

opposite direction, and then analyzing biological particles in the flush flow by a nucleic acid amplification assay.

Reconsideration and withdrawal of the obviousness rejection of claims over Cabuz in view of Iqbal et al. are respectfully requested.

It is believed the application is in condition for allowance. Reconsideration and withdrawal of all rejections of claims 1-13, and issuance of a Notice of Allowance directed to claims 18-30, are respectfully requested. The Examiner is urged to telephone the undersigned should she believe any further action is required for allowance of this application.

The fee for a one month extension of time is being paid electronically today. It is not believed any additional fee is required for entry and consideration of this Amendment.

U.S. Patent Appln. S.N. 10/579,137
AMENDMENT

PATENT

Nevertheless, the Commissioner is authorized to charge Deposit Account No. 50-1258 in the amount of any such required fee.

Respectfully submitted,

/James C. Lydon/

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Enclosure:
Petition for Extension of Time